K122922

Attachment 5
510(K) Summary
E-Beam Nd:YAG Laser System

JAN 10 2013

This 510(K) Summary of safety and effectiveness for the E-Beam Nd:YAG Laser System is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	Eclipse Aesthetics, LLC
Address:	13988 Diplomat Drive Suite 160 Dallas, TX 75234
Contact Person:	Mr. Tom O'Brien
Telephone: Fax: Email:	972-380-2911 – phone 972-380-2953 – fax tobrien@eclipsemed.com
Preparation Date:	September 12, 2012
Device Trade Name:	E-Beam Nd:YAG Laser System
Common Name:	Nd:YAG Q-Switch Laser
Classification Name:	Instrument, Surgical, Powered, laser 79-GEX, 21 CFR 878-48
Legally Marketed Predicate Device:	Lutronic Spectra Laser System K113588
Description of the E-Beam Nd:YAG Laser System:	The E-Beam Nd:YAG Laser System is a Q-Switch laser with wavelengths of 1064nm and 532nm. Optional Dye attachments to the handpiece add additional wavelengths of 585nm and 650nm. This system consists of main body, color touch screen, articulated arm hand-piece and Foot switch. The E-Beam Nd:YAG Laser System can also be used in a long pulse mode.
Intended use of the E-Beam Nd:YAG Laser System:	The E-Beam Nd:YAG Laser System in indicated for: the incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis. 532nm Wavelength (nominal delivered energy of 585 nm and 650 nm with optional dye handpieces): • Tattoo removal: light ink (red, tan, purple, orange, sky blue, green) • Removal of Epidermal Pigmented Lesions • Removal of Minor Vascular Lesions including but not limited to telangiectasias • Treatment of Lentigines • Treatment of Cafe-Au-Lait • Treatment of Seborrheic Keratoses

- Treatment of Post Inflammatory Hyper-Pigmentation
- Treatment of Becker's Nevi, Freckles and Nevi Spilus

1064nm Wavelength:

- Tattoo removal: dark ink (black, blue and brown)
- Removal of Nevus of Ota
- Removal or lightening of unwanted hair with or without adjuvant preparation.
- Treatment of Common Nevi
- Skin resurfacing procedures for the treatment of acne scars and wrinkle

None

Performance Data: None

Results of Clinical Study: None

Conclusion: The E-Beam Nd:YAG Laser System is substantially equivalent to the previously cleared predicate devices that are currently in commercial distribution.

Technical Comparison for the Q-Switch Laser

Feature	**Wavelength**	**E-Beam (Subject of this submission)**	**Spectra (K113588) (Predicate Device)**
Laser Medium		Nd:YAG	Nd:YAG
Wavelengths		1064nm / 532nm (Option: 585nm, 650nm)	1064nm / 532nm (Option: 585nm, 650nm)
Operating Mode		Q-Switched	Q-Switched
Beam Profile		Top Hat Mode	Top Hat Mode
Pulse Energy	1064nm 532nm 585nm 650nm	1200mJ 400mJ 250 mJ 150mJ	1200mJ 400mJ 250mJ 150mJ
Pulse Width		5ns – 10ns	5ns – 10ns
Spot Size	1064nm	2-8mm Colimated: 6mm	3,4,5,6,7,8mm Optional: 1,2,3,4,6,7,mm
	532nm	6.9mm	2.6, 3.4, 4.3, 5.2, 6.0, 6.9mm Optional: 0.8, 1.7, 2.6, 3.4, 4.3, 5.2, 6.0mm
	585nm	2mm	2mm
	650nm	2mm	2mm
Pulse Duration	1064nm	Single, 1,2,5,10 Hz	Single, 1,2,5,10 Hz
	532nm	Single, 1,2,4,5Hz	Single, 1,2,4,5,Hz
	585nm	Single, 1,2,4,5 Hz	Single, 1,2,4,5 Hz
	650nm	Single, 1 and 2Hz	Single, 1 and 2Hz
Beam Delivery		Articulated Arm	Articulated Arm
Aiming Beam		Diode 655nm (Red) 1mW	Diode 655nm (Red) 1mW

Technical Comparison for the Long Pulse Nd:YAG

Feature	**E-Beam (Subject of this submission)**	**Spectra (K113588) (Predicate Device)**
Laser Medium	Nd:YAG	Nd:YAG
Wavelengths	1064nm	1064nm
Operating Mode	Long Pulse	Long Pulse
Beam Profile	Top Hat Mode	Top Hat Mode
Pulse Energy	1500mJ	1500mJ
Pulse Width	300us	300us
Spot Size 1064nm	2-8mm Collimated 6mm	3,4,5,6,7,8mm Optional: 1,2,3,4,6,7,mm
Pulse Duration	Single, 1,2,5,10 Hz	Single, 1,2,5,10 Hz
Optical Deliver	Articulated Arm	Articulated Arm
Aiming Beam	Diode 655nm (Red) 1mW	Diode 655nm (Red) 1mW

Conclusion: The E-Beam Nd:YAG Laser System is substantially equivalent to the previously cleared predicate devices that are currently in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Eclipse Aesthetics, LLC
% Mr. Tom O'Brien
Chief Executive Officer
13998 Diplomat Drive
Dallas, Texas 75234

Letter dated: January 10, 2013

Re: K122922
Trade/Device Name: Tri-Beam Nd: YAG Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: December 05, 2012
Received: December 11, 2012

Dear Ms. O'Brien:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122922

Device Name: Tri-Beam Nd:YAG Laser System

Indications for Use:

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532nm Wavelength (nominal delivered energy of 585 nm and 650 nm with optional dye handpieces):

-Tattoo removal: light ink (red, tan, purple, orange, sky blue, green)
-Removal of Epidermal Pigmented Lesions
-Removal of Minor Vascular Lesions including but not limited to telangiectasias
-Treatment of Lentigines
-Treatment of Caf6-Au-Lait
-Treatment of Seborrheic Keratoses
-Treatment of Post Inflammatory Hyper-Pigmentation
-Treatment of Becker's Nevi, Freckles and Nevi Spilus

1064nm Wavelength:
-Tattoo removal: dark ink (black, blue and brown)
-Removal of Nevus of Ota
-Removal or lightening of unwanted hair with or without adjuvant preparation.
-Treatment of Common Nevi
-Skin resurfacing procedures for the treatment of acne scars and wrinkle

Prescription Use xx (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Neil R Ogden
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(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number K122922